This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K062252

SEP 27 2006

Contact person: Jason Malecka
President
IOP, Inc.
3184-B Airway Avenue
Costa Mesa, CA 92626

Date Prepared: July 24, 2006

Device Name and Classification

Proprietary Name:	Molteno3
Common Name:	Glaucoma Implant
Classification Name:	Aqueous Shunt
Product Code:	KYF
Regulation No.:	886.3920

Device Description

The Molteno3 Glaucoma implant consists of a flexible silicone translimbal tube attached to a polypropylene episcleral plate. This third generation design is intended to maximize single quadrant bleb performance and simplify insertion and postoperative management.

Indications for Use

The aqueous shunt is intended to reduce intraocular pressure in neovascular glaucoma or glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.

Summary of Testing

Current data of 44 patients receiving the GS-175mm2 were compared to historical data of the original Double Plate Molteno Implant. The outcomes through 22 months are substantially equivalent.

Substantial Equivalence Claim

The Molteno3 is identical in material composition to predicate Molteno Implant devices and has demonstrated substantially equivalent clinical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

IOP, Inc.
c/o Mr. Jason Malecka
President
3184 Airway Avenue, Building B
Costa Mesa, CA 92626

Re: K062252
Trade/Device Name: Molteno3 Glaucoma Implant
Regulation Number: 21 CFR 886.3920
Regulation Name: Glaucoma Implant
Regulatory Class: II
Product Code: KYF
Dated: July 27, 2006
Received: August 3, 2006

Dear Mr. Malecka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062252

Device Name: Molteno3 Glaucoma Implant

Indications For Use:

The Molteno3 glaucoma implants is intended to reduce intraocular pressure in neovascular glaucoma or glaucoma where medical and conventional surgical treatments have not been successful to control the progression of disease.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mychelle Vizvari
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K062252